

§ 340.5

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the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

(i) Import or offer the regulated article for entry only through any USDA plant inspection station listed in §319.37–14 of this chapter;

(ii) Notify APHIS promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with §340.5 of this part.

(g) *Withdrawal or denial of a permit.* Any permit which has been issued may be withdrawn by an inspector or the Administrator if he/she determines that the holder thereof has not complied with one or more of the conditions listed on the permit. APHIS will confirm the reasons for the withdrawal of the permit in writing within ten (10) days. Any person whose permit has been withdrawn or any person who has been denied a permit may appeal the decision in writing to the Administrator within ten (10) days after receiving the written notification of the withdrawal or denial. The appeal shall state all of the facts and reasons upon which the person relies to show that the permit was wrongfully withdrawn or denied. The Administrator shall grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator.

(h) *Courtesy permit*—(1) *Issuance.* The Administrator may issue a courtesy permit for the introduction of organisms modified through genetic engineering which are not subject to regu-

lation under this part to facilitate movement when the movement might otherwise be impeded because of the similarity of the organism to other organisms regulated under this part.

(2) *Application.* A person seeking a courtesy permit shall submit on an application form obtained from APHIS data required by paragraphs (b) (1), (2), and (5) of this section and shall indicate such data is being submitted as a request for a courtesy permit. A person should also include a statement explaining why he or she believes the organism or product does not come within the definition of a regulated article. The application shall be submitted at least 60 days prior to the time the courtesy permit is sought.

(3) *Administrative action.* APHIS shall complete an initial review within 15 days of the date of receipt of the application. If the application is complete, the responsible individual shall be notified of the date of receipt of the application for purposes of advising the applicant when the 60 day review period commenced. If the application is not complete, the responsible individual will be advised what additional information must be submitted, and shall commence the 60 day review period upon receipt of the additional information, assuming the additional information submitted is adequate. Within 60 days from the date of receipt of a complete application, APHIS will either issue a courtesy permit or advise the responsible individual that a permit is required under paragraph (b) or (c) of this section.

(Approved by the Office of Management and Budget under control number 0579–0216)

[52 FR 22908, June 16, 1987. Redesignated at 58 FR 17056, Mar. 31, 1993, as amended at 58 FR 17058, Mar. 31, 1993; 59 FR 67610, Dec. 30, 1994; 62 FR 23956, 23957, May 2, 1997; 68 FR 46436, Aug. 6, 2003; 72 FR 43523, Aug. 6, 2007]

§ 340.5 Petition to amend the list of organisms.¹⁰

(a) *General.* Any person may submit to the Administrator a petition to amend the list of organisms in §340.2 of this part by adding or deleting any genus, species, or subspecies. A petitioner may supplement, amend, or

¹⁰ See footnote 5 in §340.3.

withdraw a petition in writing without prior approval of the Administrator and without prejudice to resubmission at any time until the Administrator rules on the petition. A petition to amend the list of organisms shall be submitted in accordance with the procedures and format specified by this section.

(b) *Submission procedures and format.* A person shall submit two copies of a petition to the Animal and Plant Health Inspection Service, Biotechnology and Scientific Services, PPQ, Biotechnology Permits, 4700 River Road, Unit 147, Riverdale, Maryland 20737-1237. The petition should be dated, and structured as follows:

PETITION TO AMEND 7 CFR 340.2

The undersigned submits this petition under 7 CFR 340.4 to request that the Administrator [add the following genus, species, or subspecies to the list of organisms in 7 CFR 340.2] or [to remove the following genus, species, or subspecies from the list of organisms in §340.2].

A. Statement of Grounds

(A person must present a full statement explaining the factual grounds why the genus, species, or subspecies to be added to §340.2 of this part is a plant pest or why there is reason to believe the genus, species, or subspecies is a plant pest or why the genus, species, or subspecies sought to be removed is not a plant pest or why there is reason to believe the genus, species, or subspecies is not a plant pest. The petition should include copies of scientific literature which the petitioner is relying upon, copies of unpublished studies, or data from tests performed. *The petition should not include trade secret or confidential business information.*

A person should also include representative information known to the petitioner which would be unfavorable to a petition for listing or delisting. (If a person is not aware of any unfavorable information the petition should state, Unfavorable Information: NONE).

B. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(c) *Administrative action on a petition.*

(1) A petition to amend the list of organisms which meets the requirements of paragraph (b) of this section will be filed by the APHIS, stamped with the date of filing, and assigned a docket number. The docket number shall identify the file established for all submissions relating to the petition. APHIS, will promptly notify the petitioner in writing of the filing and docket number of a petition. If a petition does not meet the requirements of paragraph (b) of this section, the petitioner shall be sent a notice indicating how the petition is deficient.

(2) After the filing of a petition to amend the list of organisms USDA shall publish a proposal in the FEDERAL REGISTER to amend §340.2 and solicit comments thereon from the public. An interested person may submit written comments to the APHIS on a filed petition, which shall become part of the docket file.

(3) The Administrator shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either: (i) Approve the petition in whole or in part in which case the Administrator shall concurrently take appropriate action (publication of a document in the FEDERAL REGISTER amending §340.2 of this part; or (ii) deny the petition in whole or in part. The petitioner shall be notified in writing of the Administrator's decision. The decision shall be placed in the public docket file in the offices of APHIS, and in the form of a notice published in the FEDERAL REGISTER.

[52 FR 22908, June 16, 1987. Redesignated at 58 FR 17056, Mar. 31, 1993, as amended at 58 FR 17059, Mar. 31, 1993; 59 FR 67611, Dec. 30, 1994; 62 FR 23957, May 2, 1997]

§ 340.6 Petition for determination of nonregulated status.¹¹

(a) *General.* Any person may submit to the Administrator, a petition to seek a determination that an article should not be regulated under this part. A petitioner may supplement,

¹¹ See footnote 5 in §340.3.